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TRANSMITTAL FORM

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Total Number of Pages in This Submission	4

Application Number	10/665,937
Filing Date	September 18, 2003
First Named Inventor	Gunther Bellmann
Art Unit	1618
Examiner Name	Zohreh Fay
Attorney Docket Number	P02428C1

ENCLOSURES *(Check all that apply)*

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Reply Brief

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Bausch & Lomb Incorporated		
Signature	Toan P. Vo		
Printed name	Toan P. Vo		
Date	September 17, 2007	Reg. No.	43225

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Serial No. 10/665,937

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Gunther Bellmann et al.
Serial No. : 10/665,937
Filed: September 18, 2003
Title: DEXAMETHASONE GEL
Attorney Docket No. P02428-c1

: Group Art Unit: 1618
: Examiner: Zohreh Fay
: Response to Examiner's Answer

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 C.F.R. § 1.193

Sir:

In response to the Examiner's Answer mailed on July 27, 2007, please consider Applicant's Reply Brief, as shown below.

Please charge any necessary fee associated with the filing of this Reply Brief to Deposit Account No. 02-1425.

The statements regarding the real party in interest, related appeal and interference, status of the claims, status of amendments, summary of claimed subject matter, and grounds of rejection to be reviewed on appeal are the same as those presented in Applicant's Appeal Brief, filed on September 22, 2006.

Arguments

The comparative data presented in Applicant's Appeal Brief show the unexpected results that pH greater than 7.3 provides exceptional stability of dexamethasone dihydrogenphosphate disodium. Such results are not taught or suggested by the cited references, taken as a whole. In addition, there are no reasons that can prompt one of ordinary skill to make a dexamethasone gel at pH greater than 7.3 to obtain the stability of dexamethasone.

The fact that GB 2007091 discloses ophthalmic compositions in the form of a gel having a pH range that includes pH less than 7.3 shows that it never contemplates that such compositions will be unstable and become pharmaceutically ineffective after a prolonged storage. Applicant discovered such a problem when people of ordinary skill in the art had not recognized, and had not provided any solution to, the problem. Therefore, claims 7-16 are patentable. *In re Nomiya*, 509 F.2d 566, 571 (C.C.P.A. 1975) ("[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103").

The Examiner, at page 6 of the Examiner's Answer, stated that "pH is not the only variable in the comparative example." Applicant respectfully disagrees. Formulation 1 (representing a claimed composition at pH greater than 7.3) and Formulation C1 (representing composition having pH less than 7.3) differ only slightly in the amount of dexamethasone sodium phosphate (0.1107 % versus 0.0985%). Such a minor difference is not expected to have an effect on the stability of the compositions. The amount of sodium hydroxide differs slightly (0.15 % versus 0.12 %) because the difference is necessary to provide the desired pH. All other variables are kept the same in both formulations. Therefore, the comparative data show that a pH greater than 7.3 provides a stable dexamethasone gel, as claimed.

In view of the foregoing arguments, Applicant requests that the outstanding rejection be reversed and that the pending claims 7-16 be allowed.

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Respectfully submitted,

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